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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,051	01/29/2007	Chris Cindrich	P-6244/C	4876

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EXAMINER	
SCHMIDT, EMILY LOUISE	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,051	CINDRICH ET AL.	
	Examiner	Art Unit	
	Emily Schmidt	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not sufficiently disclose which features are the stanchion, the biasing element, or the interposer.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the stanchion, biasing element, and interposer must be shown or the feature(s) canceled from the claim(s). It is not clear from the

drawings which features these are as the terminology used with reference to the drawings is not found in the claims and vice versa. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention. The language used in the claims differs significantly from the language found in the specification and one of ordinary skill in the art would not be able to clearly surmise which features of the disclosed invention are being claimed thereby not fully enabling one of ordinary skill to make and use the same.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Strauss (US 4,664,654).

With regard to claim 1, Strauss teaches a device for delivering a medicament into the body of a patient by injection into or through the skin of a patient, comprising: a housing (Fig. 2 housing is taken as members 32 and 34) having a bottom surface adapted to contact the skin of a patient, a needle aperture on said bottom surface and a top surface; an injection needle (Fig. 3b member 42) adapted for penetration of tissue and for movement through the needle aperture; a reservoir (within member 34), disposed within said housing, said reservoir in fluid communication to the injection needle; a pressurization system for pressurizing the reservoir (Fig. 1 plunger 35); a shielding member (Fig. 2 member 16) adapted for movement away from the bottom surface, the shielding member having a covering portion disposed about the needle aperture, and at least one stanchion (Fig. 2 members 24) protruding from the covering portion, the shielding member having a first position wherein the stanchion of the shielding member is

initially disposed within the housing and the covering portion is substantially co-planar with the bottom surface of the housing, and a second position wherein the stanchion of the shielding member is partially withdrawn from the housing and the covering portion at least partially covers the needle (Col. 4 lines 16-20); a biasing element (Fig. 3c spring 30) disposed within the housing adapted to contact the shielding member and bias the shielding member towards the second position of the shielding member; and a movable interposer (Fig. 3a member 18) having a first position, which prevents movement of the shielding member (Fig. 3a), and a second position, which allows movement of the shielding member (Fig. 3b); wherein when the device is placed upon the skin of the patient and activated, the interposer is moved from a first position to a second position and the biasing element is allowed to bias the shielding member into the second position, thereby, as the device is removed from the skin, the shielding member emerges from the housing and at least partially covers the needle (see transition from Fig. 3a to Fig. 3c).

10. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al. (US 6,186,982 B1).

With regard to claim 2, Gross et al. teach a device for delivering a medicament into the body of a patient by injection into or through the skin of a patient, comprising: a housing having a bottom surface (Fig. 6 housing 63) adapted to contact the skin of a patient, a needle aperture on said bottom surface and a top surface; an injection needle adapted for penetration of tissue and for movement through the needle aperture (Fig. 6 see needle and aperture generally indicated at 51); a reservoir (Fig. 1 reservoir 12), disposed within said housing, said reservoir in fluid communication to the injection needle; a pressurization system for pressurizing the reservoir

(Fig. 1 pressurizing chamber 14); and a shielding member (Fig. 6 member 52) adapted for movement substantially perpendicular to the bottom surface, the shielding member having a skin contacting portion disposed about the needle aperture and is substantially covered with adhesive (Fig. 4 side 56 is covered with adhesive, Col. 11 lines 40-41), and at least one stanchion (Fig. 6 see the member extending from 64) protruding from the skin contacting portion, the shielding member having a first position wherein the stanchion of the shielding member is initially disposed within the housing and the skin contacting portion is substantially co-planar with the bottom surface of the housing, and a second position wherein the stanchion of the shielding member is partially withdrawn from the housing and the shielding member at least partially covers the needle (see transition form Fig. 5 to Fig. 6); wherein when the device is placed upon the skin of the patient, the skin contacting portion of the shielding member is temporarily adhered to the skin and when the device is removed from the skin, the adhesion of the shielding member to the skin is sufficient to move the shielding member from the first position to the second position (Col. 11 line 65-Col. 12 line 5).

With regard to claim 3, Gross et al. teach a device for delivering a medicament into the body of a patient by injection into or through the skin of a patient, comprising: a housing having a bottom surface (Fig. 6 housing 63), a needle aperture on said bottom surface and a top surface; an injection needle adapted for penetration of tissue and for movement through the needle aperture (Fig. 6 see needle and aperture generally indicated at 51); a reservoir (Fig. 1 reservoir 12), disposed within said housing, said reservoir in fluid communication to the injection needle; a pressurization system for pressurizing the reservoir (Fig. 1 pressurizing chamber 14); and a

shielding member (Fig. 6 member 52) adapted for rotational movement along an arcuate path substantially perpendicular to the bottom surface, the shielding member having a skin contacting portion disposed about the needle aperture and is substantially covered with adhesive (Fig. 4 side 56 is covered with adhesive, Col. 11 lines 40-41), and a pivot (Fig. 4 pivot 54), the shielding member having a first position wherein shielding member is substantially co-planar with the bottom surface of the housing, and a second position wherein the shielding member is rotated about the pivot and the shielding member at least partially covers the needle (see transition form Fig. 5 to Fig. 6); wherein when the device is placed upon the skin of the patient, the skin contacting portion of the shielding member is temporarily adhered to the skin and when the device is removed from the skin, the adhesion of the shielding member to the skin is sufficient to rotate the shielding member about the pivot from the first position to the second position (Col. 11 line 65-Col. 12 line 5).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767